

Remarks
11/20/03

11-20-03 03:18pm From-PILLSBURY WINTHROP CARMEL VLY.

858 509 4010

T-361 P.014/028 F-410

018813-0272487

REMARKS

Applicants note that submitted herewith is a petition under 37 CFR § 1.136 for a one month extension of time and a request that Applicants' attorneys be charged for the required fee. The Office Action mailed May 6, 2003 set an initial three (3) month period for response. With the granting of the Petition, the time period in which to submit a timely response to the Office Action mailed Monday, May 6, 2003 will be extended to September 8, 2003, since September 6, 2003 was a Saturday.

Applicants also note that they submit herewith a Terminal Disclaimer.

In response to the Notice of Draftperson's Patent Drawing Review, Applicants submit revised Figures 10A, 10B, 12A and 12B.

Claims 270 to 274 have been amended to more particularly point out and distinctly claim the isolated proteins of Applicants' invention having one or more Nematode-extracted Anticoagulant Protein domains and to correct certain minor errors pointed out by the Examiner. Applicants submit that these amends are clearly supported and give rise to no issue of new matter.

The Section 112, Second Paragraph Rejections

Claims 270 to 281 stand rejected under 35 U.S.C. § 112, second paragraph as assertedly indefinite. Applicants submit that this rejection is not well taken and that the claims as originally presented coupled with Section 112 as pending clearly comply with the second paragraph of Section 112.

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a. SEQ. ID. NO.

The Examiner has objected to the term "SEQ. ID. NO." in claims 270, 271, 272 and 273.

Applicants note that claims 270, 271, 272 and 273 have been amended to replace "SEQ. ID. NO." with "SEQ. ID. NO:". Applicants note that the present application is a continuation based on an earlier filed application and at the time this application was filed, "SEQ. ID. NO." was considered as an acceptable designation for a sequence. Applicants note that in order to expedite prosecution of this application, "SEQ. ID. NO." has been replaced with "SEQ. ID. NO:".

b. NAP

The Examiner has objected to the term "NAP" in claims 270, 271 and 272.

Applicants note that the terms "NAP" and "NAP domain" are clearly not indefinite and are explicitly defined in the application (see, e.g. page 6, line 42 to page 7, line 8).

Claim 270 has been amended to fully spell out the words that the term "NAP domain" stands for. As noted above, the abbreviation "NAP domain" is clearly defined in the specification (see, e.g., page 7, lines 5 to 8). Although Applicants believe that use of the term "NAP domain" in the claims complies with the requirements of the second paragraph of Section 112, in order to expedite prosecution, Applicants have fully spelled out the words that "NAP domain" stand for at the first instance of the use of "NAP domain" in the pending claims.

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c. AcaNAPc2

The Examiner asserts that claims 270 to 274 are indefinite due to use of the term "AcaNAPc2".

The specification clearly defines the term AcaNAPc2 as one of a number of specific recombinant proteins of Applicants' invention. Applicants note that the prefix "Aca" denotes that the source of the cDNA sequence encoding AcaNPac2 was *Ancylostoma caninum* (see, e.g., page 46, lines 30 to 40 and Figure 16). Applicants note that "AcaNAPc2/proline" was clearly identified in Example 17 at pages 116 to 117 of the specification.

In the specification the individual isolated Nematode-extracted Anticoagulant Proteins were identified by terms which included source designations. Applicants submit that the use of such terms to designate specific proteins is clearly not indefinite.

d. "Substantially the same"

The Examiner has objected to use of the term "substantially the same" in claims 270 to 274.

Applicants submit that the Examiner's position is not well taken. The term "substantially the same" is defined in the specification in terms of percent homology (See, e.g., page 12, lines 37 to 41) and, thus, is clearly not indefinite. However, in order to expedite prosecution of this application, Applicants have amended claims 270 to 274 to replace the objected to term with its definition in terms of percent homology as set forth in the specification.

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e. "About"

The Examiner appears to assert that the term "about" as part of the phrase "less than about 120 amino acid residues" in claims 270 and 271 rendered those claims indefinite.

Applicants submit that the objected to term does not render the claims indefinite. In order to expedite prosecution, Applicants have deleted "about" from the noted phrase in claims 270 and 271.

f. Claims 275 - 281

Claims 275 to 281 stand rejected as assertedly indefinite by the Examiner because those claims are asserted to

"lack essential steps as claimed in the process of treating a pathologic condition by administering a protein of claims 270-274. The omitted steps are: the site and method of administration, the therapeutically effective amount of the agent and a step whereby the desired outcome and the time for the effective treatment using the said protein can be determined."

Office Action mailed May 6, 2003 at page 3.

Applicants submit that the Examiner's position is not well taken. The specification describes methods of formulating and administering the isolated proteins of their invention to treat pathologic conditions characterized by abnormal thrombosis (see, e.g., page 66, line 41 to page 68, line 9 and page 70, lines 9 to 38).

Applicants submit that the present methods of use claims need not specify details such as sites and routes of administration, dose levels and, the like and lack of

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specification of those specifics in the claims does not render such method of use claims indefinite.

Applicants request that the Examiner reconsider the rejection of claims 275 to 281 on these grounds and withdraw it.

g. Conclusion

Applicants submit that in view of the above they have overcome the rejection of claims 270 to 281 under 35 U.S.C. § 112, second paragraph.

Applicants request that the Examiner reconsider this rejection and withdraw it.

The Obviousness-type Double Patenting Rejection

Claims 270 to 282 stand rejected under the judicially created doctrine of obviousness-type double patenting over one or more of commonly-assigned United States Patents No. 5,872,098; 5,866,542 and for 6,090,916.

Applicants note that submitted herewith is an appropriate Terminal Disclaimer and request that their attorneys' deposit account be charged for the fee.

In view of the submission of the Terminal Disclaimer, Applicants submit that they need not deal further with the present rejection.

CONCLUSION

In view of the foregoing, Applicants submit that they have overcome the outstanding rejections and claims 270 to 282 are allowable.

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Applicants request that the claims be allowed and passed to issue.

If the Examiner believes that the telephonic interview would expedite prosecution of this application, he is encouraged to telephone Suzanne L. Biggs, the undersigned Applicants' attorney.

Should any additional fees be required with the present filing, or if the fee submitted is incorrect, please charge any such fee or credit any overpayment to Deposit Account No. 50-2212, Order Number 018813-0272487 for the appropriate amount.

Respectfully submitted,

PILLSBURY WINTHROP LLP

Date: September 8, 2003 By: 

Suzanne L. Biggs
Reg. No. 30,158

11682 El Camino Real
Suite 200
San Diego, California 92130
Tel. No.: (858) 509-4095
Fax No.: (858) 509-4010